NDA 20-756/S-008

Columbia Research Laboratories, Inc. 03 APR 2001
Attention: Howard Levine, Pharm. D.
Vice President
100 North Village Avenue, Suite 32
Rockville Centre, NY 11570

Dear Dr. Levine:

Please refer to your November 9, 1998 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crinone® (progesterone gel) 8%.

This supplement proposes the following changes: revisions in the following sections of the Patient Package Insert:

1. **About CRINONE** section

2. **When you should not use CRINONE** section

3. **Risks of CRINONE** section

4. **PRECAUTIONS** section

5. **Possible side effects of CRINONE** subsection
   SIDE EFFECTS REPORTED AT A FREQUENCY OF 5% OR GREATER subsection
   SIDE EFFECTS REPORTED AT A FREQUENCY OF LESS THAN 1% subsection

6. **HOW TO USE CRINONE**, #3 and #5

7. **SPECIAL INSTRUCTIONS FOR USE AT ALTITUDES ABOVE 2500 FEET.**

We note that your additional supplemental application, S-009, submitted on August 27, 1999, and revised on February 8, March 9 and July 4, 2000, supersedes this application. Therefore, we will not review this application but it will be retained in our files.

If you have any questions, call Diane Moore, BS, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research